

CLAIMS

1. (currently amended) A stable fixed dose oral pharmaceutical formulation comprising at least one anti-infective agent selected from the group consisting of betalactams, fluoroquinolones, macrolides, and betalactamase inhibitors as a first active ingredient and at least one microorganism susceptible to said anti-infective agent but useful in preventing or minimizing adverse effects of said anti-infective agent as a second active ingredient, said anti-infective agent causing significant adverse effects which can be prevented or minimized by said microorganism, at least one of the first and second active ingredients being coated to provide a protective barrier around the said at least one of the first and second active ingredients, wherein the first and second active ingredients are contained in a single pharmaceutical formulation selected from the group consisting of a powder, a tablet and a capsule, wherein said powder, tablet, or capsule contains both said anti-infective agent and said microorganism, the protective barrier protecting the susceptible microorganism from the effect of the anti-infective agent to maintain the susceptible microorganism in a viable form for a period of at least three months.

2. (original) The formulation of claim 1 wherein said anti-infective agent is selected from the group consisting of Ampicillin, Amoxycillin, Cloxacillin, Clavulanic acid, Sultamicin, Cefuroxime axetil, Cefadroxyl, Cephalexin, Cefixime, Erythromycin, Ciprofloxacin, and combinations thereof.

3. (previously amended) The formulation of claim 2 wherein said microorganism is selected from the group consisting of Lactobacillus acidophilus,

Lactobacillus spores, Lactobacillus lactis, Streptococcus thermophilus, Streptococcus lactis, Saccromyces cerevisea, Lactobacilli GG, and combinations thereof.

4. (original) The formulation of claim 1 wherein the ratio of anti-infective agent to microorganism is in the range of 2:1 to 25:1.

5. (original) The formulation of claim 4 wherein the ratio of anti-infective agent to microorganism is about 5:1.

6. (original) The formulation of claim 1 wherein at least one of the anti-infective agent and the microorganism is coated with a physiologically acceptable excipient to provide granules of the anti-infective agent or the microorganism.

7. (original) The formulation of claim 6 wherein both the anti-infective agent and the microorganism are coated with an excipient to provide granules of the anti-infective agent and granules of the microorganism.

8. (original) The formulation of claim 7 wherein the anti-infective agent granules and the microorganism granules are formed into a layered tablet such that one layer contains the anti-infective agent and the other layer contains the microorganism.

9. (original) The formulation of claim 6 wherein the excipient is ethyl cellulose.

10. (original) The formulation of claim 6 wherein the excipient is a mixture of microcrystalline cellulose and starch.

11. (original) The formulation of claim 6 wherein the excipient is a mixture of magnesium stearate, polyplasdone XL and sodium chloride.

a) or b)

12. (currently amended) The formulation of claim 1 wherein ~~one of the first~~
~~and second active ingredients~~ is formed into a coated tablet, and wherein said coated
tablet is contained in a capsule containing the other active ingredient.

13. (original) The formulation of claim 12 wherein said tablet contains said microorganism admixed with physiologically acceptable excipients.

14. (original) The formulation of claim 1 wherein the coating comprises a compound selected from the group consisting of cellulose acetate phthalate; poly(butylmethacrylate, (2-dimethyl aminoethyl) methacrylate, methyl methacrylate); poly(ethyl acrylate, methyl methacrylate); poly(methacrylic acid, methyl methacrylate); poly(methacrylic acid, ethyl acrylate); poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride); hydrogenated Castor oil; Cetyl alcohol; diethyl phthalate; ethyl cellulose; hydroxypropyl cellulose; hydroxypropyl methylcellulose phthalate; and zein.

15. (currently amended) A stable fixed dose oral pharmaceutical tablet comprising at least one anti-infective agent as a first active ingredient and at least one microorganism susceptible to said anti-infective agent as a second active ingredient, each of the first active ingredient and an excipient forming a first discrete region of the tablet, and the second active ingredients ingredient and an excipient forming a second discrete part region of the tablet such that the first and second active ingredients are physically separated in the tablet by a coating, and the tablet includes a first region is substantially free of the second active ingredient and a the second region is substantially free of the first ingredient, the tablet maintaining the susceptible microorganism in a viable form for a period of at least three months..

not limited anti-infective agent.

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See ref.

? does it further limit (S.)

16. (currently amended) The tablet of claim 15 wherein the first region and the second region are layers of the tablet, ~~at least one of the layers comprising a coating to provide a protective barrier around the active ingredient in said at least one layer, the protective barrier protecting the susceptible microorganism from the effect of the anti-infective agent.~~

Claim 17 (canceled).

18. (currently amended) The tablet of claim 15 wherein at least one of the *a)* *b)* *are* first active ingredient and the second active ingredient is coated with an excipient to provide granules of at least one of the first and second active ingredient ingredients, the granules of said at least one of the first and second active ingredients being compressed separately to form a tablet part.

(a) & (b) does this refer to other component?

22. (currently amended) The formulation tablet of claim 4 15 wherein said anti-infective agent is selected from the group consisting of betalactams, fluoroquinolones, macrolides, and beta lactamase inhibitors.

23. (original) The formulation of claim 1 wherein said anti-infective agent causes diarrhoea, and wherein the microorganism prevents or minimizes diarrhoea induced by the anti-infective agent.

24. (original) The formulation of claim 1 wherein said anti-infective agent is a broad-spectrum antibiotic.

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with these
ingredients in
combination.*